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General Electric Company  
P.O. Box 414, Milwaukee, WI 53201

K964012

## SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87 (h).

### Identification Of Submitter

JAN - 7 1997

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GE Medical Systems  
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Date Of Preparation: September 30, 1996

### Identification Of The Product

Device Proprietary Name: GENIE Processing And Review Workstation (Genie P&R).  
Common Name: Nuclear Medicine Image Workstation  
Classification Name: Nuclear Tomography System, 892.1310  
Establishment Reg. Number: 2126677  
Manufacturing Location: GE Medical Systems  
3000 N. Grandview Blvd.  
Waukesha, WI 53188

### Marketed Devices

Predicate Device:	<u>System</u>	<u>Manufacturer</u>	<u>510(k) #</u>
	Starcam 4000	GE Medical Systems	K904174

### Device Description

Genie P&R is a computer workstation used for the retrieval, archival, processing, analysis and management of nuclear medicine images (data). It consists of a UNIX based workstation (high resolution color monitor, keyboard, mouse, CD ROM), ethernet network connection and system software. Optional optical disk archive and laser filming/color hardcopy are available.

### Indications For Use

Genie P&R is designed to display and process data acquired by nuclear medicine cameras for review by physicians. Genie P&R can retrieve data from nuclear imaging systems and archive the data.

### **Comparison With Predicate Device**

Genie P&R and the predicate device can retrieve, archive and process nuclear medicine images. A comparison of the features indicates that Genie P&R has the same intended use as the predicate device. No new safety or effectiveness concerns are raised by the design of Genie P&R.

### **Summary Of Studies**

Genie P&R can retrieve, archive, process, analyze and manage nuclear medicine images.

### **Conclusions**

In the opinion of GE Medical Systems, Genie P&R is substantially equivalent to the Starcam 4000 (image processing system only) manufactured by GE Medical Systems (510(k) # K904174). Genie P&R has the same intended use as the predicate device. No new safety or effectiveness concerns are raised by the design of Genie P&R.